

IMRI Proposed Draft Language
Based on May 7, 2008 IMRI Discussion

SECTION 2 – DEFINITIONS

(W) “INTRA-OPERATIVE MAGNETIC RESONANCE IMAGING” OR “IMRI” MEANS THE INTEGRATED USE OF MRI TECHNOLOGY DURING SURGICAL AND INTERVENTIONAL PROCEDURES WITHIN A LICENSED OPERATIVE ENVIRONMENT.

SECTION ____ . REQUIREMENTS FOR APPROVAL - APPLICANTS PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL BASED IMRI

SECTION ____ . AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL BASED IMRI SERVICE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

- (1) THE PROPOSED SITE IS A LICENSED HOSPITAL UNDER PART 215 OF THE CODE.
- (2) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS.
- (3) THE APPLICANT SHALL HAVE EXPERIENCED ONE OF THE FOLLOWING:
 - (A) AT LEAST 1,500 ONCOLOGY DISCHARGES IN THE MOST RECENT YEAR OF OPERATION; OR
 - (B) AT LEAST 1,000 NEUROLOGICAL SURGERIES IN THE MOST RECENT YEAR OF OPERATION; OR
 - (C) AT LEAST 7,000 PEDIATRIC (<18 YEARS OLD) DISCHARGES (EXCLUDING NORMAL NEWBORNS) AND AT LEAST 5,000 PEDIATRIC (<18 YEARS OLD) SURGERIES IN THE MOST RECENT YEAR OF OPERATION.
- (4) THE PROPOSED IMRI UNIT MUST BE LOCATED IN AN OPERATING ROOM.
- (5) NON-SURGICAL DIAGNOSTIC STUDIES SHALL NOT BE PERFORMED ON AN IMRI UNIT APPROVED UNDER THIS SECTION UNLESS THE PATIENT MEETS ONE OF THE FOLLOWING CRITERIA:
 - (A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR
 - (B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS, BUT IS IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS.

(6) THE APPROVED IMRI UNIT WILL NOT BE SUBJECT TO MRI VOLUME REQUIREMENTS.

(7) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE IMRI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

(8) THE APPLICANT AGREES TO OPERATE THE IMRI UNIT IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION ____ OF THESE STANDARDS.